SPECIAL CONTRIBUTIONS

Establishing the Scope and Methodological Approach to Out-of-hospital Outcomes and Effectiveness Research

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Abstract

Outcomes research offers out-of-hospital medicine a valuable methodology for studying the effectiveness of services provided in the out-of hospital setting. A clear understanding of the history and constructs of outcomes research is necessary for its integration into emergency medical services research. This report describes the conceptual framework of outcomes research and key methodological considerations for the successful implementation of out-of-hospital outcomes research. Illustrations of the specific applications of outcomes research and implications to existing methodologies are given, as well as suggestions for improved interdisciplinary research. **Key words:** outcomes research; out-of-hospital medicine; emergency medical services research. ACADEMIC EMERGENCY MEDICINE 2004; 11:1067–1073.

The provision of out-of-hospital care has come under increased scrutiny in recent years. Although it is acknowledged that timely transport is necessary for some patients, many have questioned the value of the range of out-of-hospital care services currently provided.[1–9] In the broader health care community, there is a persistent concern about the lack of proof of effectiveness for most out-of-hospital care.[10–12] Many experts agree that methodologically sound outcomes research that identifies ''what works'' in out-of-hospital care offers a meaningful response to these concerns.[1,8,13–16]

In 1994, the National Highway Traffic Safety Administration convened a workshop on methodologies for measuring morbidity outcomes in emergency medical services (EMS).[1] In response to the conclusions from this workshop, the National Highway Traffic Safety Administration funded the Emergency Medical Services Outcomes Project (EMSOP). The main objectives of the project are to identify the following: 1) priority conditions that should be emphasized in future EMS outcomes research, 2) risk-adjustment measures for the priority conditions, and 3) outcome measures for the priority conditions. Objective 1 was published in ''EMSOP I: Prioritizing Conditions for Outcomes Research.''[2] The groundwork for objectives 2 and 3 was described in two subsequent publications, EMSOP II and III.[17,18] ''EMSOP II: Developing the Foundation and Conceptual Models for Out-of-hospital Outcomes Research'' established a basic approach and framework of research models for future EMS outcomes research, and ''EMSOP III: The Role of Risk Adjustment for Out-of-hospital Outcomes Research'' presented the concept of risk adjustment and its relevance to EMS outcomes research. The EMSOP IV paper outlined pain measurement in out-of-hospital outcomes research.[19] The fifth EMSOP paper, ''Risk Adjustment

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and Outcome Measures for Out-of-hospital Respiratory Distress,'' appears in this issue of *Academic Emergency Medicine*.[20]

BACKGROUND

Health research can be thought of as five distinct disciplines: basic ''bench'' research, clinical research, epidemiologic research, outcomes research, and health systems (or services) research. Outcomes research is the most recently developed branch of health-related research and may be misunderstood by many involved in other research disciplines. A review of the development of the discipline of outcomes and effectiveness research (OER) is useful to better understand and effectively integrate outcomes research into the broader scope of EMS research as a whole.

The dramatic inflation in the cost of health care during the 1970s and 1980s promoted a political urgency to gain control over accelerating health care expenditures. It became increasingly clear that huge variations in the cost and application of health care did not correlate well with patient outcomes (i.e., more expensive health care did not necessarily translate into better patient outcomes).[21–25] Political and social concerns regarding the massive costs of health care, combined with the lack of association between cost and outcome, led to a major change in the federal approach to hospital reimbursement. The most significant resulting change was the initiation of Medicare's prospective payment system in the mid-1980s. The use of diagnosis-related groups for payment to hospitals for inpatient services created a powerful incentive to decrease the costs of patient care. No longer were hospitals reimbursed based on the care rendered. Rather, they received a ''lump-sum'' payment based on patient diagnosis.

While these dramatic changes were occurring, many politicians and health care experts identified what they perceived as a weakness in the traditional approach to medical research. It was acknowledged that great strides had been made in determining the efficacy of various treatment modalities for specific diseases. This huge knowledge base had resulted from many decades of major funding of randomized controlled trials (RCTs). This approach evaluates treatments administered by specialists who follow highly specified protocols in closely monitored settings working with carefully selected, homogeneous populations.[26] However, it was clear that this research often did not translate into either changes in physician practice or improved patient outcomes. There was a paucity of work identifying which efficacious treatments were actually effective in ''real-world'' settings.[21,25,27,28] This emerging understanding led many to join a concerted effort to develop a research discipline that would specifically identify treatment effectiveness.[14,21,23–26,29–34]

Coincidentally, the inception of diagnosis-related groups created a major concern that hospitals would be discharging patients too early. It was believed that the decision to discharge patients might be based on the number of days they had been in the hospital, rather than clearly identifying that the patients were clinically ready to leave. At congressional hearings regarding the Medicare changes, the phrase ''quicker but sicker'' captured many politicians' attention and led to major concerns about the impact of the new financial incentives.[21] The resulting quest for data related to this controversy certainly stimulated the rapid development of the ''outcomes research movement'' as a bona fide research discipline. Many believed that research methods identifying variations in practice, cost, and outcome were sorely needed to help protect citizens against profit generated by undertreatment. This led to the somewhat innovative concept of using the Medicare database to monitor the quality of hospital care. In 1986, the Health Care Financing Administration began to promote the use of this database to evaluate quality by measuring mortality rates, readmission rates, and other adverse outcomes.[21] The concept of evaluating the impact of health care on patient outcomes, however, had actually been gaining momentum for at least a decade prior due to the work of early outcomes research pioneers.[14,21,33,34] Their foundational work was very timely, and the coincidental political, social, and economic tidal waves swept their excellent (but relatively obscure) work to the forefront.

The convergence of these forces led to a series of meetings in 1987 convened by the Department of Health and Human Services that focused on whether the Medicare databases could be useful on a large scale for quality monitoring and improvement.

These landmark meetings set the stage for a major federal initiative aimed at improving the link between efficacy and effectiveness research and more clearly linking health care practice to patient outcomes.[34] Primary responsibility for moving this initiative forward was given to the newly formed Agency for Health Care Policy and Research, which was established in 1989.

THE CONCEPTUAL FOUNDATION FOR OUTCOMES RESEARCH

The leaders who initiated the development of outcomes research led to a then dramatic assumption: ''Guidance for optimal medical practice could be gleaned from analysis of data routinely gathered in the process of delivering and paying for patient care.''[21] The early years of this discipline, therefore, yielded a narrow definition for this type of research. The information that would be evaluated came from two sources: 1) ''mining'' large administrative databases (secondary analysis) in an attempt to identify the impact of care

on patient outcomes and 2) ''pooling'' studies in the literature into one large ''study'' to make presumably better conclusions about treatment and outcome (meta-analysis). These approaches were, among other issues, retrospective and dealt with often-heterogeneous populations of patients. There was little surprise that most traditional medical researchers were not enamored with this new approach. The idea that identifying what impacted patient outcomes could be accomplished by retrospectively looking at large patient populations in administratively developed databases was a huge intellectual stretch. Much heated public debate over this issue occurred in the early years of the Agency for Health Care Policy and Research.[30]

As outcomes research has matured, a less divisive approach to the scope of outcomes research has developed. The term ''outcomes and effectiveness research'' (OER, used interchangeably with outcomes research) has been used very broadly in recent years, and no single definition has been universally accepted. In general, this type of research emphasizes measuring a wide variety of patient outcomes (death, disease [physiologic abnormalities], disability, destitution [cost], dissatisfaction [patient satisfaction], and discomfort—the ''six Ds'') and attempts to identify whether efficacious interventions are effective in ''typical'' practice settings.[35–37]

The newly named Agency for Healthcare Research and Quality (AHRQ) has proposed an outline for describing how the findings of outcomes research are linked to changes in health care delivery and impact the health of patients.[20] The four levels of impact of research are shown in Table 1. The ideal situation leads to level 4 results: findings in outcomes research that are ''linked over time to increasingly concrete impacts on the health of patients.''[21] However, an extensive evaluation of the first decade of accomplishments under the auspices of the Agency for Health Care Policy and Research has shown that the vast majority of outcomes research has led only to level 1 impact.[22]

Thus, an excellent foundation has been laid for developing systematic reviews, doing rigorous meta-analyses, developing tools for measuring outcomes, and identifying techniques that minimize selection bias (e.g., ''risk adjustment''). However, the use of these tools to impact health outcomes in patients is the ultimate goal of outcomes research and, despite all of the foundational work that has been done, moving to higher levels of impact remains a challenge.

METHODOLOGICAL CONSIDERATIONS FOR EMS OUTCOMES RESEARCH AND INTEGRATION WITH OTHER RESEARCH DISCIPLINES

Although there are still some proponents of a very narrow definition of outcomes research (only research involving secondary analysis of large administrative databases, or meta-analysis), such a definition clearly would not be advantageous for the future of EMS outcomes research. For EMSOP, the investigators have chosen to accept the broader definition and framework suggested by Mendelson et al. that have been supported by the AHRQ.[21,38]

Outcomes and effectiveness research evaluates the impact of health care (including discrete interventions such as particular drugs, medical devices, and procedures as well as broader programmatic or system interventions) on the health outcomes of patients and populations. OER may include evaluation of economic impact linked to health outcomes, such as cost–effectiveness and cost–utility. OER emphasizes health problem–oriented evaluations of care delivered in general, real-world settings; multidisciplinary teams; and a wide range of outcomes, including mortality, morbidity, functional status, mental well-being, and other aspects of health-related quality of life. OER may entail any in a range of primary data collection methods and secondary (or ''synthetic'') methods that combine data from primary studies.[38]

Consistent with this approach, the EMSOP investigators strongly recommend that future efforts in EMS evaluation utilize the strengths of classic outcomes research (secondary analysis of databases and meta-analysis), epidemiologic research, systems research, and traditional clinical research methods. Existing data that are collected as a matter of routine in EMS systems and pooled information from studies that have been published are inexpensive potential sources of knowledge about the effectiveness of care. However, it is recognized that there is currently

TABLE 1. Levels of Impact of Outcomes Research Results[21]

Level 1 impact	Research findings that do not lead to a direct change in policy or practice. These products of outcomes research include new tools or methods for research and evaluation, instruments to assist in clinical decision making, developing the foundation for new questions that need to be asked, and identifying weaknesses or needed changes in current practice patterns.
Level 2 impact	Research results that are translated directly into policy or programmatic changes or development. This type of impact includes changes in legislation, bureaucracy, health care payment or planning, and clinical guidelines developed by professional organizations.
Level 3 impact	Research that leads to an actual alteration in clinical care provided. This type of research leads to things such as treatment changes by physicians or alterations in patient behavior.
Level 4 impact	Research that leads to actual alterations in patient outcomes.

a paucity of rigorous systems research and clinical trials (especially prospective RCTs) in EMS.[39] We believe that database secondary analysis is particularly useful for hypothesis generation with subsequent hypothesis testing using traditional clinical and systems research models.

It must be recognized that the databases available for EMS outcomes research are vestigial in their development and riddled with incompleteness and inaccuracy.[40,41] On the other hand, it is easy to be too enamored by the "power" of the RCT that may provide relatively few conclusions directly and readily applicable to clinical practice. It is an oversimplification to emphasize the strengths of the RCT and the weaknesses of outcomes research. Doing so misses the very real limitation of attempting to directly apply the results of many RCTs. Thus, even if vast amounts of funding were available for large numbers of RCTs in the out-of-hospital setting, profound questions about effectiveness "in the real world" would remain. We urge a balanced view that emphasizes the strengths and limitations of each type of research methodology. This approach was well stated in an AHRQ publication:

> The debate over the pros and cons of RCTs and observational studies partially obscures a basic observation that is less controversial. Different research designs are associated with different susceptibility to systemic bias. The two critical questions to ask when considering the adequacy of a particular study design then are: How likely is it that bias is affecting the results and how certain of the results is it necessary to be in order to change policy or practice?[21]

Finally, we must not underestimate the importance of accelerating the rate at which basic and clinical research findings are translated, through effectiveness research, into improved patient outcomes in EMS systems. Accomplishing this successfully will require the entire gamut of research methodologies and will require tireless efforts by career EMS researchers evaluating all aspects of EMS.

Although EMS outcomes research will include aspects of traditional outcomes research, clinical research, and epidemiology, EMS systems research will still be considered a separate discipline. However, because all EMS care is rendered within the framework of a complex, interactive system, outcomes research and EMS systems research will always be interdependent, with each being informed by the work of the other (Figure 1).

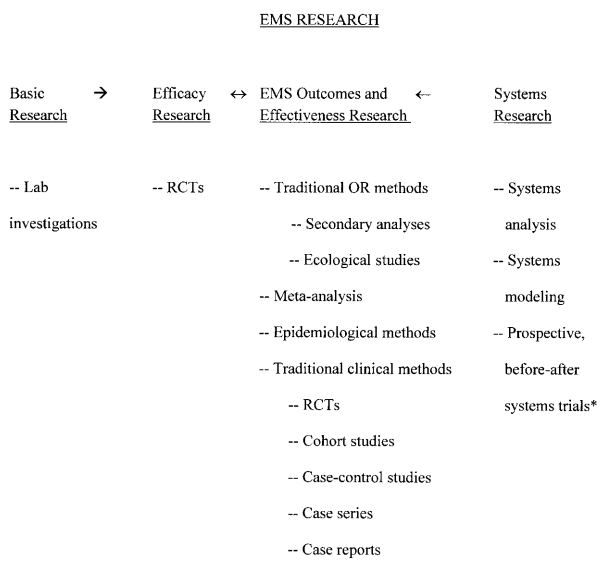

Figure 1. Emergency medical services research. *Altering the care rendered in an entire system and prospectively evaluating the effect that this change has on the outcomes in various patient populations.

IMPLICATIONS FOR FUTURE EMS OUTCOMES RESEARCH

The above discussion reveals an unfortunate reality in the history of health-related research, that is, the chasms between the disciplines of basic, clinical, epidemiologic, and systems research have lessened the potential impact of each of them. There is minimal crossover of information and expertise to such an extent that even major advances in one arena may go unnoticed by the others for years. This has left a generation of researchers who do not even understand the terminologies of the other areas, let alone have the ability to access and apply the information generated by their work. An unfortunate by-product of this history is that very few researchers are able to identify the best methodology for answering many questions. The tendency is to use the best methodology within a given research domain, often failing to recognize that a method from another domain may be far superior to meaningfully answer the question of interest.

The approach to EMS outcomes research being suggested here has the potential to minimize the problems associated with a nonintegrative model. Figure 1 depicts an overall scheme for EMS research and identifies how methods from various disciplines can be applied in an integrative way. This scheme brings up several important issues. First, no research discipline "owns" a given research methodology. For example, interventional studies are often used in traditional medical research. In this scheme, they fit both into EMS outcomes research and into EMS systems research because the prospective, before–after system trial is essentially an interventional study in which the treatment is "applied" to the entire system. Second, from the perspective of EMSOP, the classical RCT can be applied for both efficacy and effectiveness research. In this sense, an RCT may identify a drug as efficacious in children in a pediatric pulmonary clinic. An RCT may also be utilized to identify whether this efficacious drug is effective in the out-of-hospital environment. Third, various methodologies can cross several or all of the "six Ds" relevant to outcomes

research. For example, a drug may be identified as efficacious in non–out-of-hospital clinical studies and then found to be effective by an RCT in the out-of-hospital environment. It is still possible that this drug may not be found to be cost-effective by subsequent economic evaluation in the out-of-hospital setting.

Fourth, interventions or therapies found to be efficacious and effective in other environments might not be effective in the out-of-hospital setting. This obvious reality has often been ignored in the history of EMS system development. Unfortunately, this has led to a situation in which many treatments that have become ''standard of care'' may be ineffective in the out-of-hospital environment. However, at this point, ''going back'' and studying these interventions is extremely difficult or impossible due to political, social, and ethical considerations. Fifth, it makes little sense to attempt efficacy studies in the out-of-hospital environment. However, there may be a few interventions for which the pertinent treatment is essentially isolated to out-of-hospital care. For example, with the condition of out-of-hospital cardiac arrest, the meaningful ''time-efficacy curves'' for bystander cardiopulmonary resuscitation and defibrillation can really be identified only in out-of-hospital populations because of the many unique characteristics that are found in this patient group. Interestingly, as systems are found that move the time interval for collapse-to-cardiopulmonary resuscitation and collapse-to-defibrillation closer to zero, the actual ''efficacy'' and ''effectiveness'' will become essentially identical.[42,43] Sixth, the flow of information from the basic science and efficacy studies to those involved in EMS outcomes research must be encouraged. One important factor here is that the out-of-hospital environment may be the best setting to begin effectiveness trials for some interventions. In addition, this would allow EMS researchers to compete for ''early'' money available for funding initial studies for new interventions—funding that has often been exhausted by the time EMS researchers consider effectiveness trials.

Many practical examples of the value of applying outcomes research exist in the interventions frequently used during out-of-hospital care. The effectiveness of most interventions of out-of-hospital advanced life support remain unproven scientifically (e.g., lidocaine).[44] A meta-analysis of high-dose versus standard-dose epinephrine RCTs failed to show a statistical difference.[45] Several other drugs have experienced encouraging animal results, but, to the best of our knowledge, no drug has been reliably proven to increase human survival to hospital discharge following cardiac arrest.[46] The use of medical antishock trousers (MAST) became ubiquitous during the 1970s and 1980s without strong evidence of effectiveness. In 1977, the Committee on Trauma of the American College of Surgeons included the MAST suit on the list of essential equipment for ambulances. A 1999 systematic review of the MAST suit in trauma patients showed no evidence to suggest a reduction in the outcomes of mortality or length of hospital or intensive care unit stay.[47] Most of the research questions in out-of-hospital care are indeed difficult to study with traditional methods. A 2002 systematic literature review of the effect of priority dispatch of ambulances failed to find convincing evidence of impact on clinical outcomes, which highlights another potential application for outcomes research.[48] Although the transport of minor trauma victims is one of the most common uses of ambulances, meaningful knowledge regarding the effectiveness of out-of-hospital care in the condition is lacking. Out-of-hospital trauma studies have primarily focused on severely injured patients and mortality as an outcome.[10] The Ottawa Prehospital Advanced Life Support study is an example of a multidisciplinary effort that bridges traditional methods (controlled trial) with an OER or ''systems approach.'' Outcomes assessed in Ottawa Prehospital Advanced Life Support work have included death, disability (quality of life), disease status (relief of symptoms, patients' perspective of improvement), and destitution (cost).[10,49–52]

IMPLICATIONS FOR EMS DATABASES

One of the clear challenges for EMS outcomes research will be the establishment of robust databases. A long history of attempting to use standard EMS data has led to little progress.[40,41] There are few ''rich'' databases extant in EMS that provide the accuracy, completeness, and comprehensiveness to allow meaningful secondary analysis. In addition, it remains unclear whether the basic risk-adjustment measures are available in current databases to provide a foundation for even the most cursory of outcomes evaluations. For instance, if EMS personnel do not even reliably obtain blood pressure measurements in the field, how can we expect to have accurate complete data available for measures such as the Revised Trauma Score, the Glasgow Coma Scale, pulse oximetry, and the visual analog scale for pain?[53] On the other hand, these barriers are not unique to EMS and simply will require innovative solutions that have not yet been identified. Recently, the completion of the first stages of the National EMS Information System project marks significant progress on many levels.[54] The National EMS Information System project has to date revised the original 1992 National Highway Traffic Safety Administration data set, created a smaller subset database (National EMS Dataset), included outcome measures, and constructed a new data dictionary.[55]

FUTURE CHALLENGES FOR EMS OUTCOMES RESEARCH

Traditional outcomes research has very significant limitations. These flow principally from the attempt

to make conclusions from data that were collected for purposes other than research (clinical care, billing, medicolegal documentation, and so on). This is why the ten-year evaluation of the work sponsored by the AHRQ resulted in many advances in level 1 impact (methodological tools) and very few in level 2 (changing policy and guidelines), level 3 (changing physician practice and patient behavior), and level 4 (improving patient outcomes). Often the stretch between the data and the ability to make conclusions is so large as to approach uselessness when working with clinical and administrative databases. Thus, it will often be appropriate to use outcomes research methods as convenient, efficient, and inexpensive means to generate hypotheses followed by the use of clinical and epidemiological methods to test these hypotheses. One ironic encouragement for EMS researchers is the fact that general outcomes research investigators have also found it very difficult to identify patient impact. Thus, EMS research is not unique in facing formidable barriers when trying to identify effectiveness.

The ''pyramid'' of outcomes research impact (Table 1) provides an important reality check for EMS researchers. We are all tempted to conduct research that has an impact at levels 2, 3, and 4. However, these levels are built upon a large foundation of methodological development that must be accomplished before any major momentum can be established at the high impact levels. EMS outcomes research is in need of dedicated researchers who will commit a career to developing and refining methodologies that will allow the next generation of EMS investigators to make major breakthroughs that will impact patient outcomes.

In many respects, EMS perfectly lends itself to the style of classic OER. Thus, there is every reason to believe that the AHRQ will be amenable to providing major funding for well-conceived studies proposed in the out-of-hospital environment written from the classic ''outcomes perspective.'' However, it will require a significant effort to become well versed in the terminology and methodological approach of outcomes research and an even greater effort to develop innovative ways to apply classic outcomes research to EMS.

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